

Notice of Allowability

Application No.

10/733,621

Applicant(s)

VARADHACHARY ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/31/07.
2. ☒ The allowed claim(s) is/are 1,3-7,11-17 and 20-22.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 7/29/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Status of the Claims

1. Claims 1, 3-7, 11-17 and 20-22 are pending.

Applicants' amendment filed on August 31, 2007 is acknowledged. Applicants' response has been fully considered. Claims 8-10, 18-19 and 35-37 have been cancelled. Thus, claims 1, 3-7, 11-17 and 20-22 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 18 and 19 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' cancellation of the claims in the amendment filed August 31, 2007.

Withdrawn Claim Rejections - 35 USC § 103

3. The previous rejection of claims 8-10 and 35-37 under 35 U.S.C. 103(a) as being unpatentable over Nuuens *et al.* (WO 98/33509), is withdrawn in view of applicant's cancellation of the claim in the amendment filed August 31, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Allen White on October 31, 2007.

Examiner's Amendment to the Claims:

Claims 1, 3 and 15-17 have been amended as follows:

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1. (Currently amended) A method of treating a subject suffering from pain comprising the step of administering to the subject an effective amount of a lactoferrin composition comprising an N-terminal lactoferrin variant to provide an improvement in pain in the subject, wherein the pain is associated with recovery from surgery and wherein ~~any~~ the N-terminal lactoferrin variant in the lactoferrin composition has a deletion, substitution, or combination thereof, of ~~from~~ 1 to 16 N-terminal amino acid residues and the N-terminal lactoferrin variant retains the same biological function as full length lactoferrin.

3. (Currently amended) The method of claim 1 wherein said lactoferrin composition reduces the severity of ~~the patient's~~ pain in the subject.

15. (Currently amended) The method of claim 11, wherein ~~further comprising administering~~ the lactoferrin composition is administered in a delayed release formulation.

16. (Currently amended) The method of claim 15, wherein the lactoferrin composition is ~~adapted~~ formulated for release in the small intestine.

17. (Currently amended) The method of claim 15, wherein the lactoferrin composition is ~~adapted~~ formulated for release in the large intestine.

The following is an **Examiner's Statement of Reasons for Allowance**: The following references appear related to the claimed invention. Nuuens *et al.* (WO 98/33509) teach human lactoferrin (hLF) and hLF variants (e.g., N-terminal variants, hLF^{-2N}, hLF^{-3N}, hLF^{-4N}, hLF^{-5N}, lack of N-terminal Gly and Arg) can be used to treat a patient to inhibit the growth of a solid tumor; and human lactoferrin and hLF variants can be prepared in a pharmaceutical composition with a pharmaceutical carrier having the concentration of the polypeptide at least 1% to 20% by weight. Ando *et al.* (US 2004/0018190) teach lactoferrin tablets containing 50 mg of lactoferrin powder, lactose, cellulose and carboxymethylcellulose calcium salt in a dry state, and enteric lactoferrin tablets were administered to a patient suffering from a recurrence of gastric cancer after a surgical operation and retention of cancerous abdominal fluid. However, the references do not teach or suggest the use of an N-terminal lactoferrin variant in the treatment of pain which is associated with recovery from surgery. Therefore, the claims are allowable over the art of record.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

October 31, 2007